

EXPRESS MAIL NO. EL615208958US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Jurgen Kleinschmidt and Andrea Kern

Application Serial No.: To be Assigned

Filed: Herewith

For: **METHOD FOR PURIFYING AND  
CONCENTRATING AAV-2 AND  
ANTIGEN PORTIONS THEREOF**

Group Art Unit: 1648

Examiner: To be Assigned

Attorney's Docket No:  
03528.0050.CNUS01

**PRELIMINARY AMENDMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

Applicants are submitting herewith a Preliminary Amendment. The Examiner is respectfully requested to enter the amendments prior to considering the application.

**THE AMENDMENT**

**In the Specification**

Page 1, line 3, before "The present invention" insert --This application is a continuation of U.S. Application No. 09/508,037, filed June 23, 2000, which was the National Stage of International Application PCT/DE98/02569, filed September 1, 1998; which claims the priority of DE 197 38 292.4, filed September 2, 1997.--

**In the Claims**

1. (Amended) A method for purifying and concentrating AAV-2 and antigen portions thereof from a sample, said method comprising the steps of:

09/508,037-05001

[characterized in that] binding AAV-2 or antigen portions thereof [are bonded] to an activated chromatographic material which comprises antibodies linked thereto and directed against AAV-2, and

[then elution is carried out] eluting said AAV-2 or antigen portions thereof using a solution containing 0.5 to 4.5 mMgCl<sub>2</sub>.

2. (Amended) The method according to claim 1, wherein said AAV-2 is [either] a wild-type AAV-2 or a recombinantly prepared AAV-2.
3. (Reiterated) The method according to claim 1 or 2, wherein the chromatographic material is selected from the group consisting of agarose gels, dextran gels, cellulose gel matrices and acrylamide gel matrices.
4. (Amended) The method according to [any one of claims 1 to 3] claim 1 or 2, wherein the chromatographic material carries a ligand suitable for [bonding] binding proteins [, particularly antibodies].
5. (Amended) The method according to [any one of claims 1 to 4] claim 1 or 2, wherein the chromatographic material is CNBr-activated sempharose® or NHS-activated sempharose®.
6. (Amended) The method according to [any one of claims 1 to 5] claim 1 or 2, wherein the [elution] solution contains 2 to 3 M MgCl<sub>2</sub>.
7. (Amended) The method according to [any one of claims 1 to 6] claim 1 or 2, wherein the sample containing the AAV-2 [and rAAV-2, respectively,] is a cell culture supernatant or cell extracts.
8. (Amended) The method according to [any one of claims 1 to 7] claim 1 or 2, wherein the antibody directed against AAV-2 is A20 (DSM ACC2194).

9. (Amended) A kit for carrying out the method according to [any one of claims 1 to 8] claims 1 or 2, comprising:

[ - ] an antibody directed against AAV-2, and

[ - ] conventional auxiliary agents [ ,such as] selected from the group consisting of buffers, chromatographic material and controls.

### REMARKS

#### The Amendment

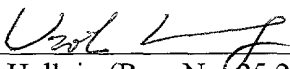
The above amendments correct the improper format of multiple dependent claims.

The above amendments also change the claim format to meet the U.S. Patent Law practice.

No new matter is added in any of the amendments. The Examiner is respectfully requested to enter all the amendments.

Respectfully submitted,

Date: June 19, 2001

  
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**CLEAN VERSION OF AMENDED PARAGRAPHS**

**In the Specification**

Page 1, line 3, before “The present invention”:

This application is a continuation of U.S. Application No. 09/508,037, filed June 23, 2000, which was the National Stage of International Application PCT/DE98/02569, filed September 1, 1998; which claims the priority of DE 197 38 292.4, filed September 2, 1997.

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**CLEAN VERSION OF ALL PENDING CLAIMS**

1. A method for purifying and concentrating AAV-2 and antigen portions thereof from a sample, said method comprising the steps of:  
binding AAV-2 or antigen portions thereof to an activated chromatographic material which comprises antibodies linked thereto and directed against AAV-2, and  
eluting said AAV-2 or antigen portions thereof using a solution containing 0.5 to 4.5 mMgCl<sub>2</sub>.
2. The method according to claim 1, wherein said AAV-2 is a wild-type AAV-2 or a recombinantly prepared AAV-2.
3. The method according to claim 1 or 2, wherein the chromatographic material is selected from the group consisting of agarose gels, dextran gels, cellulose gel matrices and acrylamide gel matrices.
4. The method according to claim 1 or 2, wherein the chromatographic material carries a ligand suitable for binding proteins.
5. The method according to claim 1 or 2, wherein the chromatographic material is CNBr-activated sempharose® or NHS-activated sempharose®.
6. The method according to claim 1 or 2, wherein the solution contains 2 to 3 M MgCl<sub>2</sub>.
7. The method according to claim 1 or 2, wherein the sample containing the AAV-2 is a cell culture supernatant or cell extracts.
8. The method according to claim 1 or 2, wherein the antibody directed against AAV-2 is A20 (DSM ACC2194).

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9. A kit for carrying out the method according to claims 1 or 2, comprising:  
an antibody directed against AAV-2, and  
conventional auxiliary agents selected from the group consisting of buffers,  
chromatographic material and controls.